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10/526,708	09/20/2005	Tami Harel	470/04441	7428

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EXAMINER

FLORY, CHRISTOPHER A

ART UNIT	PAPER NUMBER
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3762

MAIL DATE	DELIVERY MODE
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07/19/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/526,708

Applicant(s)

HAREL ET AL.

Examiner

Christopher A. Flory

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/30/2006</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Specification***

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

2. The abstract of the disclosure is objected to because it contains the phrase "said at least one electrode" in line 2. Correction is required. See MPEP § 608.01(b).

### ***Claim Objections***

3. Claim 49 objected to because of the following informalities: the portion of line two which reads "at least electrode" should be corrected to read --at least one electrode--. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 34, 36, 40 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Findl et al. (US 4,428,366, hereinafter Findl'366).

Regarding claims 34, 36 and 45, Findl'366 discloses an apparatus for blood glucose control (TITLE) comprising at least one electrode (Fig. 1, coils 24 and 26) adapted to apply an electric field to a pancreas (column 3, lines 62-64); and circuitry configured to electrify said electrode in a manner which compensates for a loss of acute response by said pancreas by significantly reducing glucose levels in a non-insulin manner (ABSTRACT; column 2, lines 45-63), the device inherently configured to apply said field when glucose levels are not elevated as well as when elevated.

Regarding claim 40, Findl'366 discloses an apparatus programmed with knowledge of a slow acting chemical-based insulin therapy provided to said pancreas (column 2, lines 14-21; column 7, lines 39-51).

6. Claims 34-36, 40 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Klettner (US 5,031,617, hereinafter Klettner'617).

Regarding claims 34 and 45, Klettner'617 discloses an apparatus for blood glucose control (TITLE) comprising at least one electrode adapted to apply an electric field to the pancreas (ABSTRACT; column 2, line 36); and circuitry configured to electrify

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said electrode in a manner which compensates for a loss of acute response by said pancreas ((ABSTRACT; column 1, lines 39-55; column 2, lines 34-45).

Regarding claim 35, Klettner'617 discloses that some applications might increase insulin production, which inherently would be quantifiable as a bolus.

Regarding claim 36, Klettner'617 discloses that glucose levels are reduced in a non-insulin manner, wherein a non-insulin manner is taken to mean a therapy in which insulin is not injected into the system.

Regarding claim 40, Klettner'617 discloses an apparatus programmed with knowledge of a slow acting chemical-based insulin therapy provided to said pancreas (column 2, lines 34-51),

7. Claims 34, 35 and 39-46 are rejected under 35 U.S.C. 102(e) as being anticipated by Houben et al. (US 5,919,216, hereinafter Houben'216).

Regarding claims 34 and 45, Houben'216 discloses an apparatus for blood glucose control (TITLE) comprising a least one electrode adapted to apply an electric field to a pancreas (ABSTRACT); and circuitry adapted to electrify said electrode in a manner which compensates for loss of acute response by said pancreas (ABSTRACT).

Regarding claim 35, Houben'216 discloses secretion of insulin in a quantity inherently quantifiable as a bolus.

Regarding claim 39, Houben'216 discloses applying control of insulin levels for at least 20% of ingestion events (Figs. 3, 7A&B and related paragraphs).

Regarding claim 40, Houben'216 discloses a slow acting chemical-based insulin therapy provided to said pancreas (ABSTRACT).

Regarding claims 41-44, Houben'216 discloses an automatic ingestion and glucose sensor for automatically detecting an event requiring an acute insulin response (Fig. 7A and related paragraphs).

Regarding claim 46, Houben'216 discloses a closed loop system (Figs. 5 and 6 and related paragraphs).

### ***Double Patenting***

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 and 27-30 of copending Application No. 10/804,560. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious

to compare the increase to a regular insulin level response in the same person, i.e. a baseline threshold.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 30-33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 35-38 of copending Application No. 10/804,560. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious to reduce glucose levels in an acute manner.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 34-44 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 39-49 of copending Application No. 10/804,560. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious to use a non-excitatory electrical field when stimulating a pancreas.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 1-29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 and 27-30 of copending Application No. 10/570,576. Although the conflicting claims are not

identical, they are not patentably distinct from each other because it is obvious to compare the increase to the regular insulin level response in the same person.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 30-33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 35-38 of copending Application No. 10/570,576. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious to reduce glucose levels in an acute manner.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. Claims 34-44 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 39-49 of copending Application No. 10/570,576. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious to use a non-excitatory electrical field when stimulating the pancreas.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefore ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re*



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*Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

16. Claims 45-56 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 52-63 of copending Application No. 10/804,560. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

17. Claims 45-56 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 52-63 of copending Application No. 10/570,576. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher A. Flory

12 July 2007

/George Manuel/  
**George Manuel**  
Primary Examiner